The AMCP's Drug Dossier Format

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Would your P&T committee appreciate receiving a consistent and evidence-based approach to the evaluation of potential new pharmaceutical products? What if you could receive this kind of information, in a timely fashion, geared to your own committee schedule? And, finally, what if this information were endorsed by a reputable national organization willing to stand behind its work? There is good news: this exact type of drug dossier does exist today, at least in part.

I learned of the drug dossiers that are available from the Academy of Managed Care Pharmacy (AMCP) during a breakout session at the exciting Third Annual Pharmacy and Therapeutics Society Meeting in Chicago, Illinois. By now, most of our readers know that the P&T Society is a nonprofit association dedicated to serving professionals involved in the delivery of high-quality, outcomes-oriented pharmaceutical care in all health care environments.

Founded in 1999, the P&T Society has grown rapidly to more than 2,800 members from multiple disciplines, including physicians, pharmacists, economists, and nurses. One of its key goals is to foster interdisciplinary collaboration, information exchange, and the pursuit of continuous quality improvement in the P&T process.

It was in this spirit that two national thought leaders, Sean Sullivan, PhD, Professor and Director of the Pharmacetical Outcomes Research and Policy Program at the University of Washington in Seattle, and Steven Avey, RPh, MS, Executive Director of the Foundation for Managed Care Pharmacy, led a workshop on the “AMCP Format.”

The AMCP originally approved the Format in October 2000. The goal of the Format for the drug dossiers was to improve the access to and transparency of the information available to P&T committees. It was suggested that the dossiers might level the playing field, in terms of alleviating the disparity of information that sometimes exists between pharmaceutical manufacturers and users. The AMCP’s leaders recognized that many nations, including Australia, Great Britain, Germany, and others, already have a somewhat comparable nationalized and evidence-based approach to providing clinicians with key information about new products.

According to Dr. Sullivan and Mr. Avey, the dossier contents go beyond the Food and Drug Administration’s (FDA’s) mandated information on safety and efficacy. The Format contents include clinical studies, economic evaluations, modeling, clinical value, and overall costs and also cover issues such as potential sources of bias. Traditional product kits are insufficient for most P&T committees in every sector of the health care economy.

Why is the availability of key information from a group like the AMCP so critically important today?

For whatever reason, the national perception about rising drug costs focuses on pharmaceuticals. We know that there has been a 50% increase in the number of prescriptions dispensed in the U.S., from nearly two billion in 1992 to three billion in 1999. The high increase in pharmacy spending is related to the more frequent use of drugs, the presence of new medications, and a modest inflation rate of 3.6% in overall prices. But in my view, perception trumps reality every time. P&T committees must effectively deal with this perception, and the AMCP dossier Format may go a long way toward providing a base of evidence for tackling this critical problem.

Mr. Avey and Dr. Sullivan were quick to point out, however, that the AMCP Format is not a panacea. It should not be construed as a sales or a marketing tool or as a simple pharmacoeconomic evaluation device. The Format establishes a standardized process of evaluation on the basis of sound scientific evidence. It provides necessary justification for restricted access to certain products; it is not simply a way to lower prescription drug costs. The Format does not offer a precise answer or define the decision-making process. It certainly cannot guarantee better overall decisions or reduced health care expenditures.

Yet despite these warnings, the AMCP Format is used by organizations across the country, including the Regence Group in Portland, Oregon; numerous Blue Cross and Blue Shield plans stretching from Hawaii to the east coast of the U.S.; and pharmacy benefit managers (PBMs) such as AdvancePCS and Cardinal Health. Taken together, the plans that are currently using the Format enroll more than 100 million members. There appears to be widespread acceptance by the pharmaceutical industry and a growing acknowledgment of the Format’s value at the individual P&T committee level.

Curiously, because of FDA regulations, the dossiers are housed at each pharmaceutical manufacturer. They are available upon request where they exist. Interested readers can visit the Web site, www.fmcpcnet.org, to learn more about the overall process.

Clearly, the AMCP Format is not the total answer to rational formulary or coverage decisions, but it is a major step in the right direction. I am going to encourage our P&T committee to branch out and collectively evaluate the AMCP Format for drug dossiers. I hope that you will encourage your P&T committee and all of its members to do the same.

As usual, I am interested in your feedback. You can reach me at my e-mail address, david.nash@jefferson.edu.